



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION**

**MEMORANDUM:**

**COMPANY NAME:** Bayer Environmental Science  
**PRODUCT NAME:** Temprid SC-F Insecticide  
**REGULATION No:** 432-1544  
**DECISION No.:** 578960  
**ACTION CODE:** R340

**DP BARCODE No.:** 464143  
**ACTIVE INGREDIENT(S):** beta-Cyfluthrin (10.5%), 118831; Imidacloprid (21%), 129099  
**MRID Nos.:** 51689301, 51689302, 51689303.  
**CR PACKAGING MANUFACTURER:** Amcor Rigid Plastics (bottle); Berry Plastics Corporation (polypropylene closure); Selig (sealing disk).  
**COUNT/FILL VOLUME:** 1 bottle and cap package/8 ml fill volume.  
**PACKAGE SIZE:** 29.4 cc round bottle with 24 mm CR-III closure.

**DATE OUT:** May 13, 2022

**SUBJECT:** Child Resistant Effectiveness (CRE) and Senior Adult Use Effectiveness (SAUE)  
Packaging Data Evaluation for Child Resistant Packaging (CRP)

**FROM:** Stephanie Suarez, CRP Reviewer  
Fungicide Branch  
Registration Division (7505P)

A handwritten signature in black ink, reading "Stephanie Suarez".

**THROUGH:** David Gardner, CRP Reviewer  
Invertebrate-Vertebrate Branch 2  
Registration Division (7505P)

A handwritten signature in black ink, reading "David Gardner".

**TO:** Scott Campbell, Risk Manager  
Venus Eagle, Product Manager 1  
Invertebrate-Vertebrate Branch 3  
Registration Division (7505P)

## BACKGROUND:

This CRP review was requested by the Invertebrate-Vertebrate 3 Branch of a certification statement for EPA Reg. No. 432-1544. This is additional CRP packaging for this product. CRP is required for this product. Bayer Environmental Science submitted a CRP Certification Statement dated September 28, 2021 in support of a new 29.4 cc round bottle with a 24 mm closure to hold 8 ml (or 0.27 fl oz) of product for Temprid SC-F Insecticide (EPA Reg. No. 432-1544). Upon reviewing the submitted CRP Certification Statement, the CRP reviewer determined that a full data review was required for this action. MRIDs 51689301, 51689302, and 51689303 were subsequently submitted to support CRP for this product. The three submitted MRIDs were evaluated and reviewed as part of this CRP review.

On April 21, 2022, the Risk Manager reached out to the company for further clarifications on behalf of the CRP team. The clarifications from the registrant are incorporated and addressed below in bold font.

When comparing the certification dated September 28, 2021 and the submitted studies, the following discrepancies were found:

- The certification stated that packages were tested with 8mL of water as placebo, however the fill volume of the contents used in the tested package was not provided in any of the studies (BYR21-13SC, MRID 51689302 and BYR21-01SC, MRID 51689303). **The registrant confirmed via email that the fill volume used in the tested package in both studies listed above was 8mL.**
- The certification stated that packages were tested with 8mL of water as placebo, however a fill volume is not mentioned at all in the adult study (MRID 51689301, Test No. BYR17-21A). **The registrant confirmed via email that the test packages used in the study were empty, so there was no fill volume. This is acceptable for adult tests; however, the Agency recommends and prefers that testing packages for all CRP studies are tested with placebos.**
- The time given to open the package for senior-adult portions were not provided in the study. **The registrant and performing facility confirmed via email that per the CPSC 16 CFR 1700.20, adults get 5 minutes to open and close the first package and 1 minute to open and close the second package.**
- The certification does not mention the adult resealing test, child or senior adult portions. The certification only mentions the percent of seniors able to open the package after initial 5 minutes. **The registrant provided a revised certification via email on May 4, 2022.**
- For MRID 51689301, Test No. BYR17-21A, the study does not list what constitutes a “failure” for the adult test. It is only stated how many senior-adults failed to open their first package. **The registrant confirmed via email that a failure is an adult not opening the package in the required time per 16CFR1700.20. There were no failures as listed in the report. All opening and closing times are in the detail section of the report.**

In addition to the discrepancies between the certification and studies, clarification was also needed regarding certain guidelines in the studies. The studies do state “This test follows the guidelines set forth by the C.P.S.C and published in the Federal Register on July 21, 1995 pgs. 37710-37744 re 16 CFR Part 1700.15 and 1700.20”. However, the specifics below are not explicitly stated:

- In all three studies, it is not explicitly stated if the tamper resistant features were removed prior to testing, as per 16 CFR 1700.20(a)(1)(ii)(A). **The conducting laboratory confirmed via email that per the protocol, the tamper resistant feature for the child test was removed prior to the test. This is required and occurs when opening and closing the closure. The adult test required the tamper evident feature stay intact until the adult tests the package at which time it becomes disengaged. The child in the resealing portion of the test would receive the second package opened and closed by the adult. Because of this the TE band would be disengaged.**
- In all three studies, it is not explicitly stated if outer packaging was provided or removed prior to testing, as per 16 CFR 1700.20(a)(1)(ii)(A). **The conducting laboratory confirmed via email that outer packaging was not included in the test. Only the bottles and closures were provided.**
- In all three studies, it is not indicated that any dialogue was provided or followed as outlined in 16 CFR 1700.20. **The conducting laboratory explained via email that this dialog was not included in the report because it is redundant. The laboratory confirmed they followed the CPSC dialogue to a tee, as stated in the report.**

**CRE STUDY RESULTS SUMMARY FOR MRID 51689302: Study BYR21-13SC Child Report.**

**(8 ml fill volume)**

<b><u>40 CFR 157.32 Requirements</u></b>	<b><u>Study Results</u></b>	<b><u>Acceptability</u></b>  A = acceptable  U = unacceptable
<b>Failure level</b>	A child failure is defined as any child who opens the package.  <i>16 CFR 1700.20 (a)(2)(ii): A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing.</i>	A
<b>Child received</b>	Each child received 24mm CR Closure on 8ml bottle filled with water.	A
<b>Test subjects</b>	50 children were tested.  The age range was 42-51 months. The children were broken into 3 groups:	A

	<p>Age 42-44 months 30% (Males: 7, Females: 8)  Age 45-48 months 40% (Males: 10, Females: 10)  Age 49-51 months 30% (Males: 8, Females: 7)</p> <p><i><u>16 CFR 1700.20 (a)(2)(i)(A and B):</u> Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. Thirty percent of the children in each group shall be of age 42-44 months, 40% of the children in each group shall be of age 45-48 months, and 30% of the children in each group shall be of age 49-51 months. The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range.</i></p>	
<b>Access rate</b>	<p>1 child was able to open their package demonstration.</p> <p>0 children were able to open their package after demonstration.</p> <p>First five minutes (before demo): 98% Effectiveness</p> <p>Full ten minutes: 98% Effectiveness</p> <p><i><u>16 CFR 1700.20 Table 1:</u> Effectiveness rate must be <math>\geq 94\%</math> in the first 5 min. and <math>\geq 90\%</math> after 10 min.</i></p>	A
<b>Sites</b>	<p>No site was used more than 20% of the time.</p> <p><i><u>16 CFR 1700.20 (a)(2)(i)(A):</u> No more than 20% of the children in each group shall be tested at or obtained from any given site.</i></p>	A
<b>Testers</b>	<p>No single tester tested more than 30% of the panel.</p> <p><i><u>16 CFR 1700.20 (a)(2)(ii):</u> No individual shall administer the test to more than 30% of the children tested..</i></p>	A
<b>Tamper Resistant Features</b>	<p>Tamper resistant features of the package have been removed prior to testing unless it is part of the CRP. Foil was removed after induction seal.</p> <p><i><u>16 CFR 1700.20 (a)(1)(ii)(A):</u> Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design.</i></p>	A
<b>Outer packaging</b>	<p>Outer packaging is not given to the child.</p> <p><i><u>16 CFR 1700.20 (a)(1)(ii)(A)(I):</u> The package is removed from the outer package, and the outer package is not given to the child.</i></p>	A
<b>Groups and Familiarity</b>	<p>Children divided into groups of two.</p> <p><i><u>16 CFR 1700.20 (a)(2)(iv):</u> The children shall be divided into groups of two. The testing shall be done in a location that is familiar to the children, for example, their customary nursery school or regular kindergarten.</i></p>	A

<b>Dialogue</b>	Script outlined in 16 CFR 1700 followed by tester.	A
<b>Findings</b>	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A
<b>Data collected and verified by:</b>	Bird Dog Marketing Group, LLC 166 Farmington Lane Lancaster, PA 17601	A

**CRE STUDY RESULTS SUMMARY FOR MRID 51689303. BYR21-01SC Child Report.**

**24mm CR-III closure on 29.4cc Round HDPE Bottle (8ml fill volume)**

<b><u>40 CFR 157.32 Requirements</u></b>	<b><u>Study Results</u></b>	<b><u>Acceptability</u></b>  A = acceptable  U = unacceptable
<b>Failure level</b>	A child failure is defined as any child who opens the package.  <i>16 CFR 1700.20 (a)(2)(ii): A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing.</i>	A
<b>Child received</b>	Each child received 24mm CR Closure on 8ml bottle filled with water; closure liner included.	A
<b>Test subjects</b>	50 children were tested.  The age range was 42-51 months. The children were broken into 3 groups: Age 42-44 months 30% (Males: 8, Females: 7) Age 45-48 months 40% (Males: 10, Females: 10) Age 49-51 months 30% (Males: 7, Females: 8)	A

	<i>16 CFR 1700.20 (a)(2)(i)(A and B): Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. Thirty percent of the children in each group shall be of age 42-44 months, 40% of the children in each group shall be of age 45-48 months, and 30% of the children in each group shall be of age 49-51 months. The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range.</i>	
<b>Access rate</b>	<p>0 children were able to open their package demonstration.</p> <p>0 children were able to open their package after demonstration.</p> <p>First five minutes (before demo): 100% Effectiveness</p> <p>Full ten minutes: 100% Effectiveness</p> <p><i>16 CFR 1700.20 Table 1: Effectiveness rate must be <math>\geq 94\%</math> in the first 5 min. and <math>\geq 90\%</math> after 10 min.</i></p>	A
<b>Sites</b>	<p>No site was used more than 20% of the time.</p> <p><i>16 CFR 1700.20 (a)(2)(i)(A): No more than 20% of the children in each group shall be tested at or obtained from any given site.</i></p>	A
<b>Testers</b>	<p>No single tester tested more than 30% of the panel.</p> <p><i>16 CFR 1700.20 (a)(2)(ii): No individual shall administer the test to more than 30% of the children tested..</i></p>	A
<b>Tamper Resistant Features</b>	<p>Tamper resistant features of the package have been removed prior to testing unless it is part of the CRP.</p> <p><i>16 CFR 1700.20 (a)(1)(ii)(A): Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design.</i></p>	A
<b>Outer packaging</b>	<p>Outer packaging is not given to the child.</p> <p><i>16 CFR 1700.20 (a)(1)(ii)(A)(I): The package is removed from the outer package, and the outer package is not given to the child.</i></p>	A
<b>Groups and Familiarity</b>	<p>Children divided into groups of two.</p> <p><i>16 CFR 1700.20 (a)(2)(iv): The children shall be divided into groups of two. The testing shall be done in a location that is familiar to the children, for example, their customary nursery school or regular kindergarten.</i></p>	A
<b>Dialogue</b>	Script outlined in 16 CFR 1700 followed by tester.	A
<b>Findings</b>	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A

<b>Data collected and verified by:</b>	Bird Dog Marketing Group, LLC 166 Farmington Lane Lancaster, PA 17601	A
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## SAUE STUDY RESULTS SUMMARY FOR MRID 51689301

### 24mm CR-III closure on 29.4cc Round HDPE Bottle (unfilled)

<u>40 CFR 157.32 Requirements</u>	<u>Study Results</u>	<u>Acceptability</u> A = acceptable U = unacceptable
<b>Failure level</b>	“A failure is an adult not opening the package in the required time per 16 CFR1700.20.”	A
<b>Tester received</b>	1 24mm CR-III Closure on 29.4cc Round HDPE bottle.	A
<b>Age and Gender distribution for adults</b>	100 senior adults were tested.  Age 50-54 years - 25% (7 males, 18 females)  Age 55-59 years - 25% (8 males, 17 females)  Age 60-70 years - 50% (15 males, 35 females)  <i><u>16 CFR 1700.20 (a)(3)(i)</u>: Use a group of 100 senior adults. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be 60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 year age group).</i>	A
<b>Access rate</b>	0 adults failed to open their first package.  0 total failures  100% Senior Adult Use Effectiveness  <i><u>16 CFR 1700.15 (b)(2)(i)</u>: Special packaging shall have a senior adult use effectiveness (SAUE) of not less than 90% for the senior-adult panel test.</i>	A



<b>Sites</b>	No site was used more than 24% of the time.  <i><u>16 CFR 1700.20 (a)(3)(i):</u> Not more than 24% of the senior adults tested shall be obtained from or tested at any one site.</i>	A
<b>Testers</b>	No single tester tested more than 35% of the panel.  <i><u>16 CFR 1700.20 (a)(3)(i):</u> No individual tester shall administer the test to more than 35% of the senior adults tested.</i>	A
<b>Tamper Resistant Features</b>	Tamper resistant features of the package have been removed prior to testing.  <i><u>16 CFR 1700.20 (a)(1)(ii)(A):</u> Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design.</i>	A
<b>Outer packaging</b>	No outer package was provided during testing.  <i><u>16 CFR 1700.20 (a)(1)(ii)(A):</u> If the outer package bears instructions for how to open or properly re-secure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer package is not counted in the times allowed for attempting to open and, if appropriate, reclose the package. If the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package will not be given to the test subject.</i>	A
<b>Dialogue</b>	Script outlined in 16 CFR 1700.20 followed by tester.	A
<b>Opening Instructions Provided:</b>	The instructions on the closure explaining how to open and resecure the package was a Pictogram.  <i><u>16 CFR 1700.20 (a)(3)(iv):</u> The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer.</i>	A
<b>Findings</b>	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A
<b>Data collected and verified by:</b>	Bird Dog Marketing Group, LLC 166 Farmington Lane Lancaster, PA 17601	A

**DESCRIPTION OF PACKAGING TESTED - MRID 51689302:**

CLOSURE MODEL AND SIZE: CAP 24mm-400 CR-III; BOTTLE: Model M24SP400 29.4cc 24mm SP400.



MATERIAL SPECIFICATION: bottle: high-density polyethylene (HDPE); closure: polypropylene.  
PACKAGE COLOR: bottle & closure: white  
MANUFACTURER: Amcor Rigid Plastics (bottle); Berry Plastics Corporation (polypropylene closure); Selig (sealing disk).  
ASTM CLASSIFICATION: Type I.  
SIZE OF PACKAGE TESTED: 29.4 cc round bottle with 24 mm CR-III closure  
FILL VOLUME: 8 ml (0.27 fl oz) water.



#### **DESCRIPTION OF PACKAGING TESTED - MRID 51689303**

CLOSURE MODEL AND SIZE: CAP 24mm-400 CR-III; BOTTLE: Model M24SP400 29.4cc 24mm SP400.  
MATERIAL SPECIFICATION: bottle: high-density polyethylene (HDPE); closure: polypropylene.  
PACKAGE COLOR: bottle & closure: white;  
MANUFACTURER: Amcor Rigid Plastics (bottle); Berry Plastics Corporation (polypropylene closure); Selig (sealing disk).  
ASTM CLASSIFICATION: Type I.  
SIZE OF PACKAGE TESTED: 29.4 cc round bottle with 24 mm CR-III closure  
FILL VOLUME: 8 ml (0.27 fl oz) water.



**DESCRIPTION OF PACKAGING TESTED - MRID 51689301:**

CLOSURE MODEL AND SIZE: 24mm CR-III Closure on 29.4cc Round HDPE Bottle.  
MATERIAL SPECIFICATION: bottle: high-density polyethylene (HDPE); closure: polypropylene.  
PACKAGE COLOR: bottle & closure: white; sealing disk:  
MANUFACTURER: Amcor Rigid Plastics (bottle); Berry Plastics Corporation (polypropylene closure); Selig (sealing disk).  
ASTM CLASSIFICATION: Type I.  
SIZE OF PACKAGE TESTED: 29.4 cc round bottle with 24 mm CR-III closure  
FILL VOLUME: None.

SAUE TEXT AND IMAGES USED DURING TEST:



**CONCLUSION:**

The revised child resistant packaging certification dated May 4, 2022 and submitted to add required child resistant packaging to this product record, is acceptable. The CRP team finds the submitted MRIDs acceptable to support EPA Reg. No. 432-1544. Based on the submitted data for MRIDs 51689301, 51689302, 51689303, these studies support a 8 ml (or 0.27 fl oz) 29.4 cc Round HDPE bottle with a 24 mm CR-III polypropylene closure, with a Selig FSM-1 unprinted sealing disk.

The picture listed above under “SAUE TEXT AND IMAGES USED DURING TEST” were tested and the results were reviewed by the CRP team. This package has been accepted by the CRP team and thus the same picture must appear on the label exactly as shown to describe the opening instructions.

CRP is required for this product. This bottle and cap package may be used to package the pending product. The MRIDs 51689301, 51689302, 51689303 must appear on the data matrix to fulfill CRP data requirements for the bottle and cap package, and the directions used in the SAUE test must appear, unaltered, on the container. Any variation in the design or manufacture (including change in color or manufacturing location) of this package from those tested in the cited studies would trigger the requirement for additional testing.

**Note to Registrant: Should any human experience epidemiological evidence and/or indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.**